

AM100123

## WHAT IS CLAIMED IS:

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1. An immunogenically active component which comprises a member selected from the group consisting of merozoite antibody inducing, inactivated *Sarcocystis neurona* cells; tachyzoite antibody inducing, inactivated *Neospora hughesi* cells; a merozoite or tachyzoite antibody inducing antigen derived from said cells; DNA derived from said cells capable of inducing a merozoite or tachyzoite antibody immune response; and a mixture thereof.

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2. The component according to claim 1 which comprises inactivated *Sarcocystis neurona* cells; an antigen derived from said cells; DNA derived from said cells; or a mixture thereof.

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3. The component according to claim 1 which comprises inactivated *Neospora hughesi* cells; an antigen derived from said cells; DNA derived from said cells; or a mixture thereof.

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4. The component according to claim 1 wherein said active component is present in sufficient quantity to provide at least  $1 \times 10^4$  inactivated cells per unit dose form.

5 5. A vaccine composition which comprises an effective immunizing amount of the immunogenically active component of claim 1, a pharmacologically acceptable carrier; and optionally an immunogenically stimulating adjuvant.

10 6. The vaccine composition according to claim 5 wherein said active component is present in sufficient quantity to provide at least  $1 \times 10^4$  inactivated cells per unit dose form.

15 7. The vaccine composition according to claim 5 wherein said active component is present in sufficient quantity to provide at least  $1 \times 10^6$  inactivated cells per unit dose form.

20 8. The vaccine composition of claim 2 wherein said active component is present in an amount sufficient to produce a merozoite inducing serum neutralizing antibody response which is protozocidal.

25 9. The vaccine composition of claim 3 wherein said active component is present in an amount sufficient to produce a tachyzoite inducing serum neutralizing antibody response which is protozocidal.

10. The vaccine composition according to claim 5 wherein the immunogenically stimulating adjuvant is present at about 1% to 50% wt/wt.

11. The vaccine composition according to claim 10 wherein said adjuvant is present at about 5% to 20% wt/wt.

5 12. The vaccine composition according to claim 10 wherein said active component comprises inactivated *Sarcocystis neurona* cells.

10 13. The vaccine composition according to claim 12 wherein said adjuvant is a metabolizable oil.

14. The vaccine composition according to Claim 13 wherein the pharmacologically acceptable carrier is a balanced salt solution.

15 15. A vaccine composition for the prevention or amelioration of EPM disease in equines comprising,  
- a first immunogenically active component selected from the group consisting of merozoite antibody inducing, inactivated *Sarcocystis neurona* cells; a merozoite antibody inducing antigen derived from said cells; DNA derived from said cells capable of inducing a merozoite antibody immune response; or a mixture thereof;  
- a second immunogenically active component selected from  
25 the group consisting of tachyzoite antibody inducing, inactivated *Neospora hughesi* cells; a tachyzoite antibody inducing antigen derived from said cells; DNA derived from said cells capable of inducing a tachyzoite antibody immune response; or a mixture thereof;  
30 - a pharmacologically acceptable carrier; and optionally an immunogenically stimulating adjuvant.

16. The vaccine composition according to claim 15 wherein said first immunologically active component comprises inactivated *Sarcocystis neurona* cells and said  
5 second immunologically effective component comprises inactivated *Neospora hughesi* cells.

17. The vaccine composition according to claim 15 wherein said first immunologically active component is  
10 present in an amount sufficient to produce a merozoite inducing serum neutralizing antibody response which is protozoicidal, and wherein said second immunologically active component is present in an amount sufficient to produce a tachyzoite inducing serum neutralizing antibody  
15 response which is protozoicidal.

18. A method for the prevention or amelioration of EPM disease in equines which comprises administering to said equine an immunogenically active component which  
20 comprises a member selected from the group consisting of merozoite antibody inducing, inactivated *Sarcocystis neurona* cells; tachyzoite antibody inducing, inactivated *Neospora hughesi* cells; a merozoite or tachyzoite antibody inducing antigen derived from said cells; DNA  
25 derived from said cells capable of inducing a merozoite or tachyzoite antibody immune response; or a mixture thereof.

19. A method for the prevention or amelioration of  
30 EPM disease in equines which comprises administering to said equine a vaccine composition which comprises,

- an effective immunizing amount of an immunogenically active component which comprises a member selected from the group consisting of merozoite antibody inducing, inactivated *Sarcocystis neurona* cells; tachyzoite antibody inducing, inactivated *Neospora hughesi* cells; a merozoite or tachyzoite antibody inducing antigen derived from said cells; DNA derived from said cells capable of inducing a merozoite or tachyzoite antibody immune response; or a mixture thereof; and

- a pharmacologically acceptable carrier; and optionally an immunogenically stimulating adjuvant.

20. A method for the prevention or amelioration of EPM disease in equines which comprises administering to

said equine a vaccine composition which comprises,

- a first immunogenically active component selected from the group consisting of merozoite antibody inducing, inactivated *Sarcocystis neurona* cells; a merozoite antibody inducing antigen derived from said cells; DNA derived from said cells capable of inducing a merozoite antibody immune response; or a mixture thereof;

- a second immunogenically active component selected from the group consisting of tachyzoite antibody inducing, inactivated *Neospora hughesi* cells; a tachyzoite antibody inducing antigen derived from said cells; DNA derived from said cells capable of inducing a tachyzoite antibody immune response; or a mixture thereof;

- a pharmacologically acceptable carrier; and optionally an immunogenically stimulating adjuvant.

21. The method according to claim 18 wherein said vaccine is administered parenterally.

22. The method according to claim 18 wherein said  
5 vaccine is administered intramuscularly.

23. A method for the cell culture propagation of *Sarcocystis neurona* or *Neospora hughesi* protozoan parasite which comprises:

- 10 a) growing a monolayer of cells having a confluency of 80%-100%;
- b) refeeding said cells with supplemented growth media;
- c) inoculating said cells with merozoites or  
15 tachyzoites;
- d) holding the inoculated cells for 4-12 days;
- e) decanting the supplemented growth media from the inoculated cells; and
- f) refeeding said cells a second time with  
20 supplemented growth media.

24. The method according to claim 23 wherein the cells are selected from the group consisting of Equine Dermal cells; Maiden Darby Bovine Kidney cells; African  
25 Green Monkey Kidney cells; Canine Monocyte cells; Mouse Monocyte cells; Fetal Rhesus Monkey Kidney cells; Feline Kidney cells, Maiden Darby Canine Kidney cells; and Baby Hamster Kidney cells.

25. The method according to claim 23 wherein the cells are Equine Dermal cells or African Green Monkey Kidney cells.